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Jon S. Wilson

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Michael P. Kenney  
Amster, Rothstein & Ebenstein  
21th Floor  
90 Park Avenue  
New York, NY 10016

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/797,363	<b>Applicant(s)</b> WILSON ET AL.	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-48, 50 and 52-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-48, 50, 52-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION*****Response to Amendment***

Amendment filed on 12/23/09 has been entered.

Claims 32-48, 50, 52-61 are present for examination.

Claims 1-32, 49 and 51 are cancelled.

***Specification***

The disclosure is objected to because of the following informalities: The 2<sup>nd</sup> paragraph at page 15, line 11 should be changed as follow:

As shown in Figure 4, the proximal extension tubes are arranged such that an included angle " $\alpha$ " exists between the longitudinal axes of the tubes 14, 16 in a free state. In a preferred arrangement, the angle " $\alpha$ " is about 5 degrees in a rest position or free state. ~~The distal~~ <sup>proximal</sup> extension tubes ~~18, 20~~ <sup>14, 16</sup> can be arranged, however, so that the angle " $\alpha$ " is any desired angle. The

15 venal proximal trunk lumen 31 is in fluid communication with the venal lumen 6 of the central

In Figs. 4-5, Applicant discusses the proximal extension tubes 14, 16 are arranged in angle " $\alpha$ ", while the distal extension tubes 18, 20 of Figs. 2-3 are arranged in angle " $\theta$ ". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 50 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Applicant discloses that the distal single lumen tubes are arranged such that an included angle " $\theta$ " exists between the longitudinal axes of the tubes 18, 20 in a free state. In a preferred arrangement,*

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*the angle "θ" ranges from about 10 degrees to about 30 degrees (see Fig. 2 and page 12, lines 17-20).*

*Applicant further discloses that the proximal extension tubes are arranged such that an included angle "α" exists between the longitudinal axes of the tubes 14, 16 in a free state. In a preferred arrangement, the angle "α" is about 5 degrees in a rest position or free state, (see Figs. 4-5 and page 15, lines 11-14).*

However, claims 32, 50 and 60 requires in opposite way with the Specification such as: the proximal single lumen tubes 14, 16 are two in number and have longitudinal axes which intersect at an included angle in a free state, the included angle being in a range from about 10 degrees to 30 degrees.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 32-34, 38, 42, 47, 50, 52, 54, 56, 58, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez (US 6,001,079).**

*As noted, Applicant defines the term "proximal" referred to those portions of a catheter inserted into an area of a patient's body such as a blood vessel; and the term "distal" for connection to a fluid exchange device, such as a dialysis machine or the like (Specification on page 11, lines 7-15).*

*Meanwhile, Pourchez discloses in a opposite way. However, to accommodate with the claimed invention, the proximal portion 5 is referred as portions of a catheter inserted into the blood vessel, and the distal portions 11 of catheters referred as portions of catheter that outwardly from the patient's body.*

**Regarding claims 32-34, 42, 47, 50, 52, 54, 58, 60,** Pourchez discloses a multi-lumen catheter comprising:

(a) a one-piece multi-tube portion 1 having a plurality of integrally formed lumens 2, 3; the multi-lumen tube portion having a proximal end 5 having a proximal end 13A, 14A, distal end at portion 6;

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(b) a distal portion 6 comprising a plurality of distal single-lumen tubes 2, 3; each distal single-lumen tube having a proximal end and a distal end, the proximal end of each distal single-lumen tube being permanently and directly connected to the distal end of the multi-lumen tube portion, without a hub, such that the lumen of each distal single-lumen tube is in fluid communication with one of the plurality of lumens of the multi-lumen tube portion;

(c) a proximal portion comprising a plurality of single-lumen tube, each proximal single lumen tube 2, 3 having a distal end 13A, 14A and a proximal end 6, the distal end of each proximal single lumen tube being permanently and directly connected to the proximal end of the multi-lumen tube portion such that the lumen of each proximal single lumen tube is in fluid communication with one of the plurality of lumens of the multi-lumen tube portion; and

a plurality of extension members 13, 14 configured at a proximal end thereof to be selectively attachable to one of the distal single lumen tubes and configured at a distal end thereof for connection to a fluid exchange device 9.

*Regarding about the limitation "proximal single lumen tubes have longitudinal axis which intersect at an included angle in a range about 10 degrees to about 30 degrees.*

As best as understood, Pourchez shows that the proximal single lumen tubes are two in number and have longitudinal axes which intersect an included angle in a free state. Pourchez does not specifically disclose the included angle being range from about 10-30 degrees.

*As noted, Applicant states that the angle " $\alpha$ " or angle " $\theta$ " can be arranged in any desired angle. (See pg 12, lines 17-20 and pg 15, lines 11-14).*

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to obtain the included angle range from 10-30 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

**Regarding claims 38 and 56**, it is well-known in the catheter art that the catheter tube is flexible and soft plastic tube with fusible material characteristic.

**Claims 35, 39-41, 43, 57, 59, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Schweikert et al. (US 6,719,749).**

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**Regarding claims 35, 39-41, 43, 57,** Pourchez discloses the invention substantially as claimed.

Pourchez does not clearly show a connector adapted to receive and hold the distal end of the distal single lumen tubes; the distal single lumen tubes having a substantially round cross-section over at least a portion of their length (claims 39, 57) or substantially D-shaped (claim 40) or round cross-section over at least a portion of their length and the proximal single-lumen tubes having a substantially D-shaped cross-section over at least a portion of their length.

Schweikert discloses similarly to the claimed invention. Schweikert further discloses a connector 50 adapted to receive and hold the distal end of the distal single lumen tubes. Schweikert further discloses that the distal single lumen tubes having a substantially round cross-section or other shapes such as D-shaped (Figs. 2 or 3B, col. 7, lines 4-11); the proximal single lumen tubes having a substantially D-shaped or other shapes over at least a portion of their length (Fig. 3A, 3C, col. 7, lines 12-19).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez with a connector, as taught by Schweikert, in order to receive and hold the distal end tube with other tubes or other medical device. The shapes of lumen for improving the speed flow of liquid.

**Regarding claims 43, 59,** Pourchez discloses the invention substantially as claimed. Pourchez does not suggest a stabilizing cuff affixed to an outer portion of the multi-lumen tube.

Schweikert discloses a stabilizing cuff 44 affixed to an outer portion of the multi-lumen tube.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez with a stabilizing cuff, as taught by Schweikert, in order to allow subcutaneous tissue or other body tissue depending upon the application of the catheter device to grow into the cuff.

**Regarding claim 61,** Pourchez discloses the invention substantially as claimed. Pourchez does not suggest plurality of selectively attachable connector hubs, each connector hubs being configured to be selectively attachable to the distal end of one of the distal single -lumen tubes.

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Schweikert discloses connector hubs 48 being configured to be selectively attachable to the distal end of the distal single-lumen tubes and being configured for selective connection to a fluid exchange device (hemodialysis device).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez with connector hubs, as taught by Schweikert, in order to connect the tubes with dialysis equipment.

**Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Schon (US 6,682,519) and Smith, III (US 4,832,687).**

Pourchez discloses the invention substantially as claimed. Pourchez does not disclose that a connector comprises means for attaching the connector to a trocar; a sheath that may be disposed over at least a portion of the distal end of the two distal single-lumen tubes and at least a portion of the connector.

Schon discloses a similar catheter device and further states that the subcutaneous tunnels are formed using a tunneling device (not shown) such as a stainless steel trocar, which, attaches to a first proximal end 59 (equivalent to distal end of claimed invention) of the first proximal portion 48 (equivalent to first distal portion of claimed invention), col. 11, lines 1-15. Schon further discloses that a second incision is made and a tunneling device such as a trocar is passed into the incision and out through the skin at the point of catheter insertion creating a subcutaneous tunnel. The catheter is attached to the tunneling device (trocar) and pulls back through the skin tunnel, col. 2, lines 42-49. In other words, there is a connector located and attached between the trocar and the proximal tube of catheter. Schon also discloses that the introducer sheath is positioned by placing a dilator/trocar device inside of the introducer sheath and passing both the dilator and the introducer sheath together into the vessel, col. 1, lines 54-59.

Smith discloses a subcutaneous tunneling device comprising: a rod/trocar 12 comprising a connector 22 attached to the distal portion of catheter 26.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez, with the connector and the introducer sheath, trocar

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connected with the catheter tubes, as taught by Schon and Smith, in order to provide the connection between the trocar and the catheter during the subcutaneous tunnel procedure.

**Claims 44-46, 53, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Schweikert et al. and further in view of Markel (US 5,624,413).**

Pourchez in view of Schweikert discloses the invention substantially as claimed. Pourchez disclose extension member 11. Meanwhile, Schweikert discloses that each extension member 50, 52 comprising a mating compression fitting 50 and a tube portion 52, a distal end of the mating compression fitting is rigidly attached to a proximal end of the tube portion and the mating compression fitting allows fluid communication there through. Schweikert further discloses the fitting 48 which may be slidable along the extension tubes 38, 39, but quick connects, either by snap-fit, screw thread or other suitable closure, preferably screw thread as show in lines A of Fig. 1.

Neither Pourchez nor Schweikert disclose that the mating compression fitting is attached to a cannula.

Markel discloses a similar catheter system comprising a each extension member comprising a mating compression fitting (including 88, 90) and a tube portion 92, wherein a proximal end of the mating compression fitting (including 88, 90) is rigidly attached to a cannula 98, a distal end of the mating compression fitting is rigidly attached to a proximal end of the tube portion and the mating compression fitting allows fluid communication between the cannula 98 and the tube portion 92; wherein the mating compression fitting further comprises a thread connection portion (located between element 86 and 88), this limitation is similar to limitation of claim 55.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez in view of Schweikert, with the compression fitting attached to the cannula, as taught by Markel, in order to connect the extension tube with other catheter tube for fluid communication through the catheter.



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**Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Herweck et al. (US 5,197,976).**

Pourchez in view of Schweikert discloses the invention substantially as claimed. Pourchez does not disclose the single-lumen tube includes indicia indicating a discrete flow path through the catheter.

Herweck discloses that the tube structure can include identifying indicia, such as colored lines to distinguish each structure from other (col. 2, lines 45-50 or in claim 5 of the Invention of Herweck). For example, the device of Herweck comprises two different flow paths (phantom arrow) in Fig. 1, the tube structure can be different colored lines so that the user can distinguish between the in or out flow direction of fluids.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez, with an indicia, as taught by Herweck, in order to distinguish between the flow path of fluid lines.

### ***Response to Arguments***

Applicant's arguments filed 12/23/09 have been fully considered but they are not persuasive.

Applicant argues that Pourchez, alone or in combination with the other applied references, does not teach or suggest a multi-lumen catheter in which, proximal single lumen tubes have longitudinal axes which intersect at an included angle in a free state, in included angle being in a range from about 10 degrees to about 30 degrees, as recited in claims 32, 50 and 60.

In response, claims 32, 50 and 50 involve 112th, 1st paragraph issue as discussed above. However, Applicant clearly states that either distal single lumen tubes are arranged such that an included angle "θ" exists between the longitudinal axes of the tubes 18, 20 in a free state. In a preferred arrangement, the angle "θ" ranges from about 10 degrees to about 30 degrees. The distal extension tubes 18, 20 can be arranged, however, **so that the angle "θ" is any desired angle** (emphasis added), (see Fig. 2 and page 12, lines 17-20); Or the proximal extension tubes are arranged such that an included angle "α" exists between the longitudinal axes of the tubes 14, 16 in a free state. In a preferred arrangement, the angle "α" is about 5 degrees in a rest position or free state. The proximal extension tubes 14, 16 can be

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arranged, however, **so that the angle "α" is any desired angle** (emphasis added), (see Figs. 4-5 and page 15, lines 11-14).

Similarly, Pourchez clearly shows that either the proximal extension tubes 13, 14 or the distal extension tubes at location 11 are arranged in angle exists between the longitudinal axes of the tubes. Therefore, the range of the angle is about 10-30 degrees or 5 degrees has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Furthermore, the instant disclosure describes these parameters as being merely preferable, and does not describe it as contributing any unexpected result to the device. As such, these parameters are deemed matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. See also *In re Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) where the Federal Circuit held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and the device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/  
Examiner, Art Unit 3763